

WHAT IS CLAIMED IS:

1. An implantable osmotic pump for delivering a pharmaceutical agent to a patient, comprising:

a catheter;

5 an osmotic engine;

a pharmaceutical agent compartment;

a volume of pharmaceutical agent that includes Sufentanil within the pharmaceutical agent compartment, and

a piston disposed within the compartment, the compartment being configured such that the
10 osmotic engine causes the piston to travel within the compartment along an arcuate path and deliver the pharmaceutical agent through the catheter when the pump is implanted in the patient, wherein the pump is configured for:

a daily delivery rate of Sufentanil of up to about 125 micrograms per day when the catheter is placed intraventricularly;

15 a daily delivery rate of Sufentanil of up to about 250 micrograms per day when the catheter is placed intrathecally;

a daily delivery rate of Sufentanil of up to about 750 micrograms per day when the catheter is placed epidurally;

20 a daily delivery rate of Sufentanil of up to about 1500 micrograms per day when the catheter is placed subcutaneously, and

a daily delivery rate of Sufentanil of up to about 1500 micrograms per day when the catheter is placed intravascularly.

2. The pump of Claim 1, wherein the compartment is disposed at least partially around the osmotic engine.

5 3. The pump of Claim 1, wherein the osmotic engine includes a base, a cylindrical wall attached to the base and a free end opposite the base.

4. The pump of Claim 1, further including a housing configured to enclose at least the osmotic engine and the compartment.

5. The pump of Claim 4, wherein the housing includes a first housing half and a
10 second housing half that mates with the first housing half.

6. The pump of Claim 5, wherein each of the first and second housing halves define a saucer shape.

7. The pump of Claim 5, wherein each of the first and the second housing halves are substantially circular in shape.

15 8. The pump of Claim 5, wherein the first housing half defines a substantially circular opening.

9. The pump of Claim 1, further including a membrane enclosure, the membrane enclosure being partially surrounded by the osmotic engine and including an initial dose semipermeable membrane that is configured to allow water from the patient to reach the osmotic
20 engine when the pump is implanted.

10. The pump of Claim 9, wherein the pump is configured to deliver an initial dose of the pharmaceutical agent to the patient at a selected initial infusion rate, the selected initial infusion

rate being related to at least one of a thickness, a composition and a surface area of the initial dose semipermeable membrane.

11. The pump of Claim 9, wherein the initial dose semipermeable membrane is fitted with an initial dose impermeable membrane that initially seals the initial dose semipermeable
5 membrane.

12. The pump of Claim 11, further including a volume of a saturated saline solution between the initial dose semipermeable membrane and the initial dose semipermeable membrane.

13. The pump of Claim 9, further including a dose escalation assembly fitted in the membrane enclosure, the dose escalation assembly being adapted to selectively increase an amount
10 of water from the patient that reaches the osmotic engine when the pump is implanted.

14. The pump of Claim 13, wherein the dose escalation assembly includes a first impermeable membrane configured to enable water from the patient to reach the osmotic engine through a first fluid path only after being breached.

15. The pump of claim 13, wherein the dose escalation assembly includes:
15 a first impermeable membrane configured to enable water from the patient to reach the osmotic engine through a first fluid path only after being breached, and

a second impermeable membrane configured to enable water from the patient to reach the osmotic engine through a second fluid path only after being breached, the first path being distinct from the second path.

20 16. The pump of Claim 15, wherein the first and second impermeable membranes are disposed in the membrane enclosure in a stacked configuration wherein the first impermeable membrane must be breached before the second impermeable membrane can be breached.

17. The pump of Claim 15, wherein the first fluid path includes a first semipermeable membrane and wherein the second fluid path includes a second semipermeable membrane that is distinct from the first semipermeable membrane.

18. The pump of Claim 17, wherein the pump is configured to deliver a first dose of the
5 pharmaceutical agent to the patient at a selected first infusion rate and a second dose of the pharmaceutical agent to the patient at a selected second infusion rate that is greater than the first infusion rate, the selected first and second infusion rates being related to at least one of a thickness, a composition and a surface area of the first and second semipermeable membranes, respectively.

19. The pump of Claim 1, wherein the osmotic engine includes a hygroscopic salt.

10 20. The pump of Claim 1, wherein the osmotic engine includes an absorbent polymer.

21. The pump of Claim 20, wherein the absorbent polymer includes a material selected from a group including poly(acrylic acid), potassium salt; poly(acrylic acid), sodium salt; poly(acrylic acid-co-acrylamide), potassium salt; poly(acrylic acid), sodium salt-graft-poly(ethylene oxide); poly (2-hydroxethyl methacrylate); poly(2-hydroxypropyl methacrylate) and
15 poly(isobutylene-co-maleic acid) or derivatives thereof.

22. The pump of Claim 1, wherein the compartment has a substantially constant inner diameter over a length thereof.

23. The pump of Claim 1, wherein the compartment has a non-constant inner diameter over a length thereof.

20 24. The pump of Claim 1, wherein the catheter includes a radiopaque tip.

25. The pump of Claim 1, wherein the piston includes one of a sphere, an elastomeric cylinder and an elastomeric conical section.

26. The pump of Claim 25, wherein the piston includes at least one of stainless steel, a refractory metal, plastic, nylon and rubber.

27. The pump of Claim 1, wherein the sufentanil is at a concentration up to about 500,000 µg/mL.

5 28. The pump of Claim 13, wherein the dose escalation assembly includes:

a first saturated saline solution between the first impermeable membrane and the first semipermeable membrane, and

a second saturated saline solution between the second impermeable membrane and the second semipermeable membrane.

10 29. A method of delivering a pharmaceutical agent to a patient, comprising steps of:

implanting a pump into the patient, the pump including a pump engine and a compartment adapted to store a pharmaceutical agent, and

causing a piston to travel a distance within the compartment along an arcuate path and to deliver a dose of pharmaceutical agent out of the compartment.

15 30. The method of claim 29, wherein the implanting step is carried such that the pharmaceutical agent is delivered one of intravascularly, subcutaneously, epidurally, intrathecally and intraventricularly.

31. The method of Claim 30, wherein the pharmaceutical agent includes Sufentanil and wherein the pump is configured for:

20 a daily delivery rate of Sufentanil of up to about 125 micrograms per day when the implanting step is carried out such that the pharmaceutical agent is delivered intraventricularly;

a daily delivery rate of Sufentanil of up to about 250 micrograms per day when the implanting step is carried out such that the pharmaceutical agent is delivered intrathecally;

a daily delivery rate of Sufentanil of up to about 750 micrograms per day when the implanting step is carried out such that the pharmaceutical agent is delivered epidurally;

5 a daily delivery rate of Sufentanil of up to about 1500 micrograms per day when the implanting step is carried out such that the pharmaceutical agent is delivered subcutaneously, and

a daily delivery rate of Sufentanil of up to about 1500 micrograms per day when the implanting step is carried out such that the pharmaceutical agent is delivered intravascularly.

32. The method of claim 30, wherein travel of the piston within the compartment causes
10 a delivery of a volume up to about 20 μ L/day over a treatment period.

33. The method of claim 29, further comprising the step of selectively increasing the dose in a stepwise manner over a treatment period without removing the pump from the patient.

34. The method of claim 33, wherein the pump engine includes an osmotic engine and wherein the pump includes an initial dose semipermeable membrane initially exposed to the
15 patient and at least one second semipermeable membrane initially not exposed to the patient and wherein the increasing step includes a step of selectively exposing the at least one second semipermeable membrane to the patient.

35. The method of Claim 29, wherein the pump the engine includes an osmotic engine in fluid communication with the piston and wherein the causing step includes a step of increasing a
20 volume of the osmotic engine.

36. A pump, comprising:

a pump engine;

a compartment adapted to store a fluid, the compartment being disposed at least partially around the pump engine, and

5 a piston disposed within the compartment, the compartment and the engine being configured to cause the piston to travel within the compartment along an arcuate path and to force a volume of the fluid out of the pump.

37. The pump of Claim 36, wherein the pump engine includes an osmotic engine.

38. The pump of Claim 36, wherein the fluid includes a pharmaceutical agent.

39. The pump of Claim 36, further including a catheter coupled to the compartment.

10 40. The pump of Claim 36, wherein the pump is fully implantable in a body and wherein pump engine and the compartment are enclosed in a biocompatible pump housing.

41. The pump of claim 36, further including a dose escalation assembly, the escalation assembly being configured to selectively increase the dose of fluid delivered.

15 42. The pump of Claim 36, wherein the dose escalation assembly comprises means for increasing the dose delivered in a stepwise manner.

43. The pump of Claim 36, wherein the piston includes one of a sphere, an elastomeric cylinder and an elastomeric conical section.